DEPARTMENT OF HEALTH

Repeal of State of Hawaii Public Health Regulations
Chapter 30 and Adoption of Chapter 11-110,
Hawaii Administrative Rules
SEP 3 2002
(Date of adoption)

SUMMARY

1. State of Hawaii Public Health Regulations Chapter 30 is repealed.

2. Chapter 11-110, Hawaii Administrative Rules, entitled "Clinical Laboratories and Laboratory Personnel," is adopted.

DEPARTMENT OF HEALTH

State of Hawaii Public Health Regulations Chapter 30, REPEALED
[OCT 19 2002]

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 110

CLINICAL LABORATORIES AND LABORATORY PERSONNEL

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Historical Note: Chapter 110 of Title 11, Hawaii Administrative Rules, is based substantially upon Chapter 30, Public Health Regulations. [Eff 12/26/74; R OCT 19 2002]

SUBCHAPTER 1

GENERAL PROVISIONS

§11-110-1 Purpose. The purpose of this chapter is to protect the health, welfare, and safety of the public by establishing minimum licensure standards for clinical laboratories and clinical laboratory personnel. [Eff OCT 19 2002] (Auth: HRS §§321-11, §11-110-2, 321-13, 321-14, 321-15) (Imp: HRS §§321-11, 321-13, 321-14, 321-15)

§11-110-2 Definitions. As used in this chapter:

"Accredited college or university" means a regionally accredited college or university in the United States.

"Accredited program" means a structured training program accredited by a nationally recognized accrediting agency or an association that is acceptable to the department.

"Agency acceptable to the department" means a national certifying agency of laboratory personnel that is acceptable to the Secretary of the United States Department of Health and Human Services, including, but not limited to, the American Society of Clinical Pathologists and the National Credentialing Agency for Laboratory Personnel.

"Clinical laboratory" means a facility where the microbiological, serological, chemical, hematological, biophysical, toxicological, cytological, pathological, or other examinations of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment of a disease or assessment of a medical condition.

"Clinical laboratory director" or "laboratory director" means a person who is responsible for the administrative, technical, and scientific operation of a clinical laboratory including the supervision of procedures for testing and the reporting of the test results.

"Clinical laboratory owner" means a person or entity in whom is vested the ownership rights of control, possession, and dominion of a clinical

laboratory.

"Clinical laboratory personnel" includes clinical laboratory directors, medical technologists, clinical laboratory specialists, cytotechnologists, and medical laboratory technicians.

"Clinical laboratory sciences" include clinical chemistry, clinical microbiology, hematology, clinical immunology, immunohematology, cytology, cytogenetics, and histology.

"Collecting depot" means a place separate from patient care facilities and where specimens are received or taken from the body of an individual for laboratory examination elsewhere.

"Department" means the state department of health.

"Director of health" or "director" means the director of the state department of health or the director's authorized agent.

"Full-time experience" means employment or activity that constitutes at least forty hours a week or its equivalent. For instance, one year of full-time experience is equivalent to two years of half-time experience.

"Laboratory acceptable to the department" means a clinical laboratory licensed by the department or licensed by another state whose requirements are equal to or more stringent than Hawaii standards, a clinical laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, Title 42, Code of Federal Regulations, Part 493, a clinical laboratory certified under Title 21, Code of Federal Regulations, Parts 600-680, or a clinical laboratory acceptable to the United States Department of Health and Human Services.

"Laboratory specialty" means clinical chemistry, hematology, immunohematology, microbiology, immunology, cytology, and cytogenetics.

"Person" means an individual, firm, association, corporation, partnership, organization, municipality, political subdivision, or any other forms of entity, whether organized for profit or not.

"Pertinent laboratory experience" means performing laboratory tests in a clinical laboratory acceptable to the department, and which are appropriately complex for the category of licensure sought, as determined by the director. [Eff OCT 19 2002] (Auth: HRS §§321-11, 312-13, 321-14, 321-15) (Imp: HRS §§321-11, 321-13, 321-14, 321-15)

§11-110-3 (Reserved).

§11-110-4 Severability clause. Should any section, paragraph, sentence, clause, phrase, or application of this chapter be declared unconstitutional or invalid for any reason, the remainder of this chapter shall not be affected thereby. [Eff OCT 19 2002] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

SUBCHAPTER 2

CLINICAL LABORATORIES

§11-110-5 Applicability of subchapter 2 and exemptions. Subchapter 2 applies to all clinical laboratories within the State of Hawaii, except laboratories that:

(1) Are operated by the United States government;
(2) Are operated and maintained exclusively for research and teaching purposes, involving no patient services whatsoever;
(3) Are operated by a licensed physician performing diagnostic tests solely for the physician's own patients. However, such clinical laboratories shall be required to comply with section 11-110-12(e) and may be required by the department to demonstrate proficiency;
(4) Are operated by a police department of any county and perform breath alcohol analysis; or
(5) Conduct any study of public health importance with the written approval of the director of health. [Eff OCT 19 2002] (Auth: HRS §§321-1, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110-6 Clinical laboratory licensure.

(a) No person shall establish, conduct, maintain, or operate a clinical laboratory in this State without a valid and effective clinical laboratory license

issued by the department.

(b) All applications for original licensure shall be approved or denied no later than sixty calendar days following the date that the complete application is received.

(c) A clinical laboratory license shall be effective for a period of not more than twenty-four months.

(d) The clinical laboratory director shall display the license issued to the laboratory by the department in a prominent place in the laboratory. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-7 Requirements for clinical laboratory license.

(a) Every person who intends to operate a clinical laboratory shall file with the department an application on a form prescribed and furnished by the department.

(b) Each applicant for a clinical laboratory license or renewal of a clinical laboratory license shall demonstrate to the satisfaction of the department that the laboratory has at a minimum:

(1) A licensed clinical laboratory director;

(2) Licensed clinical laboratory personnel for the laboratory tests to be performed; and

(3) Premises, equipment, and methodologies that are adequate for the volume and type of tests the clinical laboratory will perform, and are approved by the department.

[Eff OCT 19 2002] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110-8 Clinical laboratory director's responsibilities.

(a) The director of a clinical laboratory shall be responsible for:

(1) The technical and scientific operation of the laboratory, including the selection and supervision of test procedures, reporting of results, continuous application of quality control procedures, and active participation in the operations to such extent as may be

necessary to assure compliance with the rules and directives of the department;

(2) The proper performance of all tests in the laboratory; and

(3) The technical supervision of qualified laboratory personnel.

(b) Commensurate with the scope and complexity of the services provided, the clinical laboratory director shall ensure that the staff is qualified, sufficient in number, and receives in-service training to maintain competency to perform test procedures and to report test results promptly and proficiently.

(c) If the clinical laboratory director is absent for more than one month, the associate clinical laboratory director or, if there is none, a person whose qualifications are satisfactory to the department and who has been approved by the department prior to being appointed, shall assume the responsibilities of the laboratory director.

(d) When a clinical laboratory director's employment is terminated for any reason, the owner of the clinical laboratory shall notify the department within fourteen days of the termination of employment. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110-9 Responsibilities of medical technologists, clinical laboratory specialists, cytotechnologists, and medical laboratory technicians. Clinical laboratory personnel are responsible for specimen processing, test performance, and for reporting test results. Each licensee performs only those clinical laboratory tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training, or experience, and technical abilities. Each individual performing testing must:

(1) Follow the laboratory's procedures for specimen handling and processing, test analysis, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control

activities, instrument and procedural calibrations and maintenance performed:

(4) Follow the laboratory's established policies and procedures whenever the test systems are not within the laboratory's established acceptable levels of performance;

(5) Identify problems that may adversely affect test performance or reporting of test results and either correct the problems or immediately notify the laboratory director or designated supervisor; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance and specifications. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110-10 Licensure inspections. All applicants for renewal of a clinical laboratory license and all licensed clinical laboratories shall permit the inspection of the laboratory, its records, material, equipment, and methodology, by a representative of the department any time during the laboratory working hours. The department may accept the on-site inspections of the College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, Health Care Financing Administration, Center for Disease Control and Prevention, National Institutes of Health, and other accrediting agencies, provided that these agencies have standards that are equal to or more stringent than the requirements of this chapter. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §§321-11, 321-20)

§11-110-11 Licensure limitations.

(a) A clinical laboratory shall perform only those tests within the specialties or subspecialties which are stated on its license. The license shall include only those specialties or subspecialties which the clinical laboratory director or technical personnel are qualified to perform. The clinical laboratory director shall notify and seek approval from the department in writing of any changes of specialties or subspecialties at least thirty days prior to the occurrence of each change.

(b) No clinical laboratory license may include the specialty of anatomic pathology or cytology unless tissue specimens or specimens for cytologic examinations are to be examined on the premises by a pathologist or a physician who has demonstrated to the satisfaction of the department that he or she is qualified by education, training, and experience to perform such procedures. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-12 Clinical laboratory procedures.

(a) All technical procedures used in a clinical laboratory shall be standard procedures which are generally accepted by authorities in the specialties of laboratory medicine or which are approved by the department. Each technical procedure shall be initially approved, signed, and dated by the laboratory director. Each change in a procedure shall be approved, signed, and dated by the laboratory director.

(b) Except as otherwise provided in this chapter, a clinical laboratory shall examine specimens only at the request of a person authorized by law to receive and interpret the laboratory test results. A verbal request shall be followed by a written request to the clinical laboratory within forty-eight hours. If the clinical laboratory does not receive the written request within that period, it shall note that fact in the record of daily accession of specimens as required in this chapter.

(c) The result of a test shall be reported directly and only to the person described in subsection (b) or the referring laboratory. No diagnosis or prognosis or suggested treatment may be made part of the laboratory report, except for reports made by a licensed physician if such reports are signed by the physician.

(d) All specimens accepted by a clinical laboratory shall be tested on its premises. However, specimens for infrequently performed tests, or those not included within the specialties or subspecialties stated on its license, or those requiring specialized equipment and skill, may be forwarded to another laboratory acceptable to the department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding clinical laboratory. The forwarding laboratory shall send a

transcript of such reports to the person who requested the tests and shall indicate thereon the name and address of the laboratory in which the test was actually performed.

(e) The clinical laboratory director shall report to the department all laboratory findings which indicate the presumptive presence of any disease required to be reported pursuant to chapter 11-156, entitled "Communicable Diseases," or as required by other statutes or rules. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-13 Safety and sanitation requirements.

(a) All clinical laboratories shall be maintained and operated in a manner which will not expose employees, patients, or the general public to undue physical, chemical, and biological hazards.

(b) Laboratories shall be well-ventilated, well-lighted, and convenient to sink, water, gas, suction, and properly grounded electrical outlets. There shall be sufficient space to perform the services provided by the laboratory with optimum accuracy and safety.

(c) All culture processes involving potential sources of aerosolized pathogens shall be performed in a biological safety cabinet. All procedures which involve liberation of toxic, corrosive, or explosive substances shall be performed in a fume hood.

(d) Cylinders of compressed gases shall be secured in a manner to prevent falling or being knocked over.

(e) Blood and blood components used for transfusion shall be stored in a refrigerator that maintains a temperature between 2° and 6° Centigrade. This shall be verified continuously by a recording thermometer and confirmed by a system of audible and visible alarms which are monitored at all times. Stored blood shall be inspected daily.

(f) Flammable or combustible liquids shall be stored in compliance with applicable state and federal standards.

(g) Laboratories using corrosive materials shall have appropriately located safety showers and eye wash stations.

(h) Adequate numbers and appropriate types of fire extinguishers shall be placed in convenient

locations, inspected at least annually, and recharged if necessary.

(i) Syringes, needles, lancets, or other blood drawing devices shall be decontaminated and disposed of in a manner approved by the department.

(j) Diagnostic use of radioactive isotopes shall conform to the laws of the State of Hawaii and the regulations of the United States Nuclear Regulatory Commission.

(k) Cultures and specimens and all other potentially infectious materials shall be decontaminated in accordance with state rules prior to disposal.

(l) All sewage and liquid wastes shall be discharged into a municipal sewage system or disposed in a manner approved by the department.

(m) All personnel handling open specimens shall wear protective clothing and other safety gear as is necessary. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-14 Specimen identification and examination.

(a) Every specimen received for testing shall be labeled and numbered, or otherwise appropriately identified, and listed in an accession log in chronological order.

(b) Every tissue specimen and non-gynecological cytology specimen shall be examined and reported upon by a pathologist who is certified, or eligible for certification, in anatomic pathology by the American Board of Pathology or a physician who has demonstrated to the satisfaction of the department that he or she has the equivalent of such certification.

(c) Every abnormal specimen for exfoliative cytology shall be examined and reported upon by a qualified pathologist.

(d) Initial examination or "screening" of specimens for exfoliative cytology and reporting of negative gynecologic specimens, may be made by a person who is licensed as a cytotechnologist.

(e) Every laboratory shall have a written and documented procedure to assure that an appropriate number of negative gynecological specimens are re-evaluated.

(f) If the component to be tested in a specimen

is perishable, labile, or otherwise subject to deterioration, such specimen shall be tested promptly after collection. If a specimen is transported or stored, it shall be properly preserved, refrigerated, frozen, or otherwise appropriately treated to maintain it in as close to its original state as allowed by current technology.

(g) Every clinical laboratory shall promptly notify the sender of any specimen that is not satisfactory for testing for any reason.

[Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-15 Records.

(a) Each clinical laboratory shall retain a duplicate copy of the original report made for each specimen received for analysis for at least two years.

(b) Each clinical laboratory shall have a record indicating the daily accession of specimens. The record shall contain the following information:

(1) The laboratory number or other identification of each specimen received by the laboratory;
(2) The name or other unique identification of the person from whom the specimen was taken;
(3) The name of the person or clinical laboratory who submitted the specimen;
(4) If the request for the test was verbal and not followed by a written request as required by this chapter, a written statement to that effect shall be made;
(5) The date and time, if applicable, the specimen was collected;
(6) The date and time the specimen was received by the clinical laboratory;
(7) If the specimen is forwarded to another laboratory, the name of the other laboratory, the date the specimen was forwarded to the other laboratory, the date it was tested, and the date the report of the findings of the tests was received from the other laboratory;
(8) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, turbid, etc.);
(9) The actual tests performed;
(10) The results of the laboratory tests or cross reference to results;

(11) The date a report was sent to the department pursuant to section 11-110-12(e); and

(12) The name, the initials, or other identification of the person who performed each test, or in the case of a test involving performance by more than one person, the name, the initials, or other identification of the persons who actually supervised the test.

(c) All records and reports of each test performed, including the original or duplicates of original reports from another laboratory, shall be kept on the premises of the laboratory and shall be provided to representatives of the department on request. All other records shall be retained by the laboratory for a period of at least two years, except for those records or reports that must be retained for a longer period under state or federal law.

(d) Each clinical laboratory shall:

(1) Maintain current personnel records in the clinical laboratory or the personnel office. These records shall include a resume of each employee's training and experience, including dates of previous and current employment, and continuing education; and

(2) Annually submit a list of its clinical laboratory personnel, including their license number, expiration date, and job title, to the department. [Eff OCT 19 2002] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110-16 Collecting depot.

(a) A clinical laboratory may maintain collecting depots after first obtaining written approval from the department for the establishment of each depot.

(b) A collecting depot shall:

(1) Have a current, written manual of methods and procedures used to ensure the satisfactory collection of specimens including patient preparation prior to specimen collection, proper specimen identification, and storage and preservation of specimens;

(2) Be adequate for the proper collection of specimens. This shall include adequate and proper staffing, plumbing, heating, cooling,

lighting, ventilation, refrigeration, electrical services, sanitary conditions, fire protection within the collecting depot and its surroundings, water supply, sewage disposal, procedures for handling and disposal of specimens, and safety measures for personnel; and

(3) Keep and maintain a record indicating the daily accession of specimens. The record shall contain the following information:

(A) The name or other unique identification of the person from whom the specimen was taken;

(B) The name of the person who requested the test;

(C) The date and time when the specimen was received or when it was collected;

(D) Signature or suitable identification of the person receiving or collecting the specimen;

(E) The type or source of the specimen; and

(F) The test(s) requested.

(c) No laboratory tests shall be performed in a collecting depot. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-17 Proficiency testing and quality assurance programs for clinical laboratories.

(a) All clinical laboratories shall demonstrate to the department proficiency in the performance of the tests offered by the clinical laboratory through state-approved proficiency testing programs. The cost of proficiency testing programs shall not be borne by the department. All clinical laboratories are required to demonstrate and maintain proficiency in each of the specialties or subspecialties for which it is licensed.

(b) Each clinical laboratory shall maintain a properly documented quality assurance program that is acceptable to the department. The quality assurance program shall be designed to assure, on a continuous basis, the reliability of all laboratory results. All facilities, equipment, and instruments shall have inherent capabilities consistent with the services offered and shall be maintained in good operating condition.

(c) There shall be a written preventive

maintenance program which details periodic inspection for proper operation of each piece of equipment and instrument, a written program for validation and calibration of equipment, a dependable reagent and glassware evaluation system, and a continuous surveillance of results. In each case, appropriate records showing the dates of inspections, validation, evaluation, and significant actions taken in response to revealed defects, shall be maintained.

(d) Current manuals of methods and technical procedures shall be maintained by the laboratory and shall be made available to clinical laboratory personnel and, for inspection, to representatives of the department. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-18 Unlawful practices.

(a) A clinical laboratory license shall not be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall the license be valid for any location other than that for which it was issued.

(b) No establishment other than a clinical laboratory or a collecting depot conducted in conformity with section 11-110-16, shall receive specimens for the purpose of laboratory examination to obtain information for diagnosis, prevention, or treatment of a disease or the assessment of a medical condition. [Eff OCT 19 2002] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110-19 Violations.

(a) If the department determines that any requirements of this subchapter have been violated, the department shall notify the licensee of the violation in writing. In the notice the department shall set forth the specific violations and may do one or more of the following:

(1) Impose fines;
(2) Place restrictions on the license;
(3) Revoke the license;
(4) Establish a specific time for the correction of each correctable violation; and
(5) Approve or disapprove a written plan of correction submitted by the licensee for each

correctable violation.

(b) If violations are not corrected within the time specified in the notice or in the accepted plan of correction, the department may do one or more of the following:

(1) Impose fines;

(2) Place restrictions on the license, or

(3) Revoke the license.

(c) The license of a clinical laboratory may be revoked, suspended, or denied for violations of the provisions of this chapter, or one or more of the following reasons:

(1) A false statement made on an application for license or any other document submitted to the department;

(2) Knowingly permitting unauthorized persons to perform technical procedures or issue or sign reports;

(3) Consistent errors in performance of laboratory procedures, based on faulty technique or controls;

(4) Dishonest reporting of test results;

(5) Knowingly performing a test and rendering a report thereon to a person not authorized by law to submit the specimens;

(6) Failure to make a report of a communicable disease pursuant to section 11-110-12(e); and

(7) Any other activity that is detrimental to the public health.

(d) The director may suspend the license of a clinical laboratory to perform tests in one or more of the specialties or subspecialties stated on a license, for a period not to exceed ten calendar days, pending the final determination of charges against the laboratory, whenever there has been error in the laboratory tests to such a degree that in the opinion of the director it poses an imminent and substantial danger to the health or life of a patient or member of the public.

(e) Each decision of the department shall become final twenty days after service unless the alleged violator submits a written request for a hearing before the director pursuant to chapter 91, Hawaii Revised Statutes. Upon receipt of the request, the director shall notify the alleged violator of the specific time and location of the hearing.

(f) All written plans of correction shall be

submitted to the department within ten days of the department's notification to the laboratory owner or laboratory director of the deficiency or deficiencies. [Eff OCT 19 2002] (Auth: HRS §§321-11, 321-13, 321-20) (Imp: HRS §§321-11, 321-13)

§§11-110-20 to 21 (Reserved).

SUBCHAPTER 3

CLINICAL LABORATORY PERSONNEL

§11-110-22 Clinical laboratory personnel license.

(a) No person shall serve as a clinical laboratory director, medical technologist, clinical laboratory specialist, cytotechnologist, or medical laboratory technician without a current and valid clinical laboratory personnel license issued by the department.

(b) Application forms for licensure may be obtained by request from the state laboratories division, department of health.

(c) The clinical laboratory personnel licenses are:

(1) Clinical laboratory director;

(2) Medical technologist;

(3) Clinical laboratory specialist;

(4) Cytotechnologist; and

(5) Medical laboratory technician.

(d) Every applicant for a clinical laboratory personnel license shall provide documents verifying education, training, and employment experience requested on the application form.

(e) The specific education, training, and experience requirements for a clinical laboratory personnel license under subsection (d) may be waived by the director if the applicant presents evidence to the satisfaction of the director that the applicant's combination of education, training, and experience is substantially equivalent to the specific clinical licensure requirements.

(f) All applications for original licensure shall be approved or denied no later than sixty calendar days

following the date that the application is complete with all required documents verifying education, training, experience and full payment of all required fees. All applications for license renewal or restoration shall be approved or denied no later than sixty calendar days following receipt of a completed renewal or restoration application and the full payment of all required fees.

(g) After January 31, 2003, all clinical laboratory personnel licenses shall expire on January 31 of each odd-numbered year.

(h) All valid clinical laboratory personnel licenses in effect immediately prior to the effective date of this subchapter shall remain in effect until their renewal dates. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14, 321-15) (Imp: HRS §§321-13, 321-14, 321-15)

§11-110-23 (Reserved).

§11-110-24 Clinical laboratory director. A license to practice as a clinical laboratory director may be issued to an applicant who meets one of the following requirements:

(1) Is a physician licensed to practice medicine or osteopathy in the State of Hawaii and is:
    (A) Certified in anatomical or clinical pathology or in one of the clinical laboratory specialties by the American Board of Pathology or the American Osteopathic Board of Pathology; or
    (B) Certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, or other national certification board which is approved by the director, in one of the clinical laboratory specialties;
(2) For the subspecialty of oral pathology only, is a physician licensed to practice medicine or osteopathy in the State of Hawaii and is certified by the American Board of Oral

Pathology, the American Board of Pathology, or the American Osteopathic Board of Pathology;

(3) Holds a doctoral degree from an accredited college or university in a chemical, physical, biological, or clinical laboratory science, and:

(A) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, or other certifying agency acceptable to the department, in one of the clinical laboratory specialties; and

(B) Has at least two years of pertinent full-time laboratory experience in one or more of the clinical laboratory specialties, including at least one year of clinical laboratory supervisory experience in a laboratory acceptable to the department. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110-25 Medical technologist (Clinical laboratory scientist). A license to practice as a medical technologist may be issued to an applicant who is certified as a medical technologist by an agency acceptable to the department, and who meets one of the following requirements:

(1) Holds a bachelor's degree in medical technology from an accredited college or university and successful completion of an accredited program of medical technology;

(2) Holds a bachelor's degree in a chemical, physical, or biological science from an accredited college or university, including:

(A) Sixteen semester hours in chemistry courses of which at least six semester hours are in introductory college chemistry that are acceptable toward a major in chemistry; and

(B) Sixteen semester hours in biology courses that are pertinent to the clinical laboratory sciences and are

acceptable towards a major in the biological sciences; and

(C) Three semester hours in college mathematics; and

has completed one year of full-time clinical laboratory experience that included a minimum of two months each in clinical chemistry, clinical microbiology, hematology, immunology and immunohematology in a laboratory acceptable to the department;

(3) Has successfully completed a minimum of ninety semester hours (or their equivalent) in an accredited college or university and has successfully completed a course of training of at least twelve months in an accredited program of medical technology.

(A) For an applicant who completed training prior to September 15, 1963, the ninety semester hours shall include at least twenty-four semester hours of chemistry and biology courses of which:

(i) At least six semester hours were in introductory college chemistry and at least three semester hours were in other chemistry courses; and

(ii) At least twelve semester hours were in biology courses pertinent to the clinical laboratory sciences; or

(B) For an applicant who completed training after September 14, 1963, the ninety semester hours shall include:

(i) Sixteen semester hours in chemistry courses that include at least six semester hours in introductory college chemistry that are acceptable toward a major in chemistry;

(ii) Sixteen semester hours in biology courses that are pertinent to the clinical laboratory sciences and are acceptable towards a major in the biological sciences; and

(iii) Three semester hours of college level mathematics.

[Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110-26 Clinical laboratory specialist. A license to practice as a clinical laboratory specialist in hematology, immunohematology, clinical chemistry, immunology, microbiology, or cytogenetics may be issued to an applicant who is certified by an agency acceptable to the department, in the laboratory specialty for which licensure is sought and who meets one of the following requirements:

(1) Holds a bachelor's degree in a pertinent chemical, physical, or biological science, as determined by the director, from an accredited college or university and has successfully completed at least one year of pertinent full-time clinical laboratory experience in a laboratory acceptable to the department or one year of training in an accredited program, or both, in the specialty for which licensure is sought; or

(2) Has successfully completed at least ninety semester hours (or their equivalent) from an accredited college or university and one year of training in a accredited program in the laboratory specialty for which licensure is sought.

(A) An applicant who completed training prior to September 15, 1963 must have twenty-four semester hours in chemistry and biology courses of which:

(i) Six semester hours were in introductory college chemistry and three semester hours were in other chemistry courses; and

(ii) Twelve semester hours were in biology courses pertinent to the clinical laboratory specialty for which licensure is sought;

(B) An applicant who completed training after September 14, 1963 needs:

(i) Sixteen semester hours in chemistry courses that includes six semester hours in introductory college chemistry that are acceptable towards a major in chemistry;

(ii) Sixteen semester hours in biology courses that are pertinent to the

clinical laboratory specialty for which licensure is sought and are acceptable towards a major in the specialty; and

(iii) Three semester hours of college level mathematics.

[Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110-27 Cytotechnologist. A license to practice as a cytotechnologist may be issued to an applicant who is certified in cytotechnology by an agency acceptable to the department, and who has met one of the following requirements:

(1) Holds a bachelor's degree in cytotechnology from an accredited college or university;

(2) Holds a bachelor's degree in a chemical, physical, or biological science and has successfully completed an accredited program in cytotechnology;

(3) Before September 1, 1992, has successfully completed at least sixty semester hours (or their equivalent) in an accredited college or university with at least twelve semester hours in science, eight of which are in biology; and:

(A) Completed twelve months of training in an accredited program of cytotechnology; or

(B) Completed six months of formal training in an accredited program of cytotechnology and six months of full-time experience in a clinical laboratory under the direct supervision of a pathologist who is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;

(4) Before September 1, 1994, has full-time experience of at least two years within the preceding five years examining slide preparations under the supervision of a pathologist who is certified in anatomic pathology by the American Board of Pathology

of the American Osteopathic Board of Pathology or other physician certified as a specialist in cytology and before January 1, 1969, must have:

(A) Graduated from high school; and

(B) Completed six months of training in cytotechnology in a laboratory that is acceptable to the department and was directed by a pathologist or other physician certified as a specialist in cytology. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§§11-110-28 to 29 (Reserved).

§11-110-30 Medical laboratory technician (clinical laboratory technician). A license to practice as a medical laboratory technician may be issued to an applicant who is certified as a medical laboratory technician by an agency acceptable to the department, and who has met one of the following qualifications:

(1) Holds an associate degree from an accredited program for medical laboratory technicians;

(2) Has successfully completed at least sixty semester hours (or their equivalent) which included courses in chemistry and biology from an accredited college or university and has either of the following:

(A) Completed an accredited program for medical laboratory technicians; or

(B) Completed an advanced military medical laboratory technician course in the United States Armed Forces of at least fifty weeks duration and held the military enlisted occupational specialty of Medical Laboratory Specialist (laboratory technician) within the five years immediately prior to date of application for licensure.

[Eff OCT 19 2002] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13. 321-14)

§11-110-31 (Reserved).

§11-110-32 Exemptions.

(a) Any new clinical laboratory personnel licensing requirement that is added by this subchapter shall not be a bar to the license renewal of any person who held a clinical laboratory personnel license immediately prior to the effective date of this subchapter.

(b) Any person requesting renewal of a current and valid clinical laboratory supervisor's license issued prior to the effective date of this subchapter shall be granted a medical technologist, clinical laboratory specialist, or cytotechnologist license in place of the person's clinical laboratory supervisor's license. The clinical laboratory supervisor's license will not be granted after the effective date of this subchapter. The licensee shall pay the current renewal fee. [Eff OCT 19 2002] (Auth: HRS §321-13) (Imp: HRS §321-13)

§11-110-33 Revocation, suspension, restriction, limitation, or denial of a clinical laboratory personnel license. (a) A clinical laboratory personnel license may be revoked, suspended, restricted, limited, or denied for one or more of the following reasons:

(1) A false statement or material omission made on an application for licensure or license renewal or on any other document submitted to the department;

(2) False reporting or knowingly permitting false reporting of test results;

(3) Conviction, whether by nolo contendere or otherwise, of a felony or any penal offense substantially related to the qualifications, functions, or duties of clinical laboratory personnel under the laws of any state of the United States or of the federal government. The record of conviction or a certified copy thereof shall be conclusive evidence of such conviction;

(4) Allowing unauthorized persons or unqualified

persons to perform technical laboratory procedures or to issue or to sign reports;

(5) Excessive number of errors in the results of tests performed, supervised, or directed by the licensee;

(6) Performing a test and rendering a report thereon to a person who is not authorized by law to submit the specimen;

(7) Any conduct that poses an immediate and serious threat to patient health and safety, including performing or supervising laboratory tests for which the licensee is unqualified to supervise or to perform;

(8) Being habituated to the excessive use of drugs or alcohol; or being addicted to, dependent on, or a habitual user of a narcotic, barbiturate, amphetamine, hallucinogen, or other drug having similar effects;

(9) Practicing in a clinical laboratory while the ability to practice is impaired by alcohol, drugs, or mental instability;

(10) Violation of chapter 576A, Hawaii Revised Statutes; or

(11) Revocation, suspension, or any other disciplinary action by another state of a license or certificate for reasons as provided in this subsection or any disciplinary action of a practice privilege by any agency of the United States.

(b) The director of health may summarily suspend a person's clinical laboratory personnel license for a period not to exceed thirty working days for the following conditions:

(1) Pending the final determination of charges against the licensee that there has been an error in the results of tests performed by the licensee or under the supervision of the licensee to such a degree that the director of health finds it poses an imminent and substantial danger to the health or life of a patient or members of the public; or

(2) When the conduct of the licensee poses an imminent and substantial danger to the health or life of a patient or the public.

(c) A clinical laboratory personnel license will be suspended or denied whenever the Child Support

Enforcement Agency issues a certification of noncompliance for license suspension or denial. The clinical laboratory personnel license shall be restored or may be granted after the Child Support Enforcement Agency issues an authorization to release license suspension or denial.

(d) An applicant who is denied a clinical laboratory personnel license shall be entitled to an administrative hearing pursuant to chapter 91, HRS. [Eff OCT 19 2002] (Auth: HRS §§321-11, 321-13; SLH 1997, Act 293) (Imp: HRS §§91-13.1, 321-11, 321-13, 321-15, 321-20)

§11-110-34 (Reserved).

§11-110-35 Fees.

(a) The department shall not issue an original license or renew a license without first collecting the appropriate fee:

(1) Non-refundable application fees for licenses:

(A)	Clinical laboratory director	$25
(B)	Medical technologist	$25
(C)	Clinical laboratory specialist	$25
(D)	Cytotechnologist	$25
(E)	Medical laboratory technician	$25

(2) License fee:

(A)	Clinical laboratory director	$50
(B)	Medical technologist	$40
(C)	Clinical laboratory specialist	$40
(D)	Cytotechnologist	$40
(E)	Medical laboratory technician	$40

(3) License renewal fee:

(A)	Clinical laboratory director	$40
(B)	Medical technologist	$30
(C)	Clinical laboratory specialist	$30
(D)	Cytotechnologist	$30
(E)	Medical laboratory technician	$30

(4) Restoration fee: $20

(b) All fees shall be collected by the department at the time of application for initial licensure, license renewal, and restoration of license.

(c) Requests for license renewal and the renewal fees should be received by the department by January 31 of each odd-numbered year starting in the year 2003.

The failure, neglect, or refusal of any person holding such license to request renewal or to pay the renewal fee after thirty days of delinquency shall constitute a forfeiture of the person's license; provided that a forfeited license may be restored upon written application and payment of all delinquent fees. If a license is forfeited for one year and less than two years, the department may request that the applicant submit additional information and evidence satisfactory to the department including passing of an examination, showing that the applicant remains fit to practice as a clinical laboratory person before the license is restored. A license that has been forfeited for two years or more shall not be restored and a new application for license shall be required.

(d) A fee shall be paid for the restoration of a license suspended pursuant to chapter 576A, Hawaii Revised Statutes. [Eff OCT 19 2002] (Auth: HRS §§321-11.5, 321-14, 321-15) (Imp: HRS §§321-14, 321-15)

§11-110-36 Violations. Anyone who violates any provision of this subchapter may be fined not more than $1000 for each day of violation, may be subject to revocation, suspension, restriction, or limitation of licensure or to any other remedies or provisions of section 321-10, Hawaii Revised Statutes, and may have recourse to an administrative hearing in accordance with chapter 91, Hawaii Revised Statutes, and the department's rules of practice and procedure. [Eff OCT 19 2002] (Auth: HRS §§321-13, 321-20) (Imp: HRS §§321-11, 321-13, 321-20)

DEPARTMENT OF HEALTH

Title 11, Chapter 110, State of Hawaii Administrative Rules, on the Summary Page dated SEP 3 2002 following public hearings held on May 24, 2002 after public notice was given in the Honolulu Star-Bulletin on April 22, 2002.

These rules shall take effect ten days after filing with the Office of the Lieutenant Governor.

_____
BRUCE S. ANDERSON, Ph.D., M.P.H.
Director of Health

APPROVED AS TO FORM:

_____
Deputy Attorney General

_____
BENJAMIN J. CAYETANO
Governor
State of Hawaii

Date: 10/9/02

Filed: OCT 09 2002